

PATENT COOPERATION TREATY

Patent Mail Received

From the INTERNATIONAL SEARCHING AUTHORITY

JUL 22 2008

PCT

NOTIFICATION OF TRANSMITTAL OF
 THE INTERNATIONAL SEARCH REPORT AND
 THE WRITTEN OPINION OF THE INTERNATIONAL
 SEARCHING AUTHORITY, OR THE DECLARATION

To:
 DORSEY & WHITNEY LLP
 Attn. Abelev, Gary
 250 Park Avenue
 New York NY 10177
 ETATS-UNIS D'AMERIQUE

(PCT Rule 44.1)

Applicant's or agent's file reference 189149/PCT	Date of mailing (day/month/year) 17/07/2008	FOR FURTHER ACTION See paragraphs 1 and 4 below
International application No. PCT/US2008/057450	International filing date (day/month/year) 19/03/2008	
Applicant THE GENERAL HOSPITAL CORPORATION		

1. The applicant is hereby notified that the international search report and the written opinion of the International Searching Authority have been established and are transmitted herewith.

Filing of amendments and statement under Article 19:

The applicant is entitled, if he so wishes, to amend the claims of the International Application (see Rule 46):

When? The time limit for filing such amendments is normally two months from the date of transmittal of the International Search Report.

Where? Directly to the International Bureau of WIPO, 34 chemin des Colombettes
1211 Geneva 20, Switzerland, Fascimile No.: (41-22) 338.82.70

For more detailed instructions, see the notes on the accompanying sheet.

2. The applicant is hereby notified that no international search report will be established and that the declaration under Article 17(2)(a) to that effect and the written opinion of the International Searching Authority are transmitted herewith.

3. **With regard to the protest** against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:

- the protest together with the decision thereon has been transmitted to the International Bureau together with the applicant's request to forward the texts of both the protest and the decision thereon to the designated Offices.
- no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

4. Reminders

Shortly after the expiration of **18 months** from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau as provided in Rules 90bis.1 and 90bis.3, respectively, before the completion of the technical preparations for international publication.

The applicant may submit comments on an informal basis on the written opinion of the International Searching Authority to the International Bureau. The International Bureau will send a copy of such comments to all designated Offices unless an international preliminary examination report has been or is to be established. These comments would also be made available to the public but not before the expiration of 30 months from the priority date.

Within **19 months** from the priority date, but only in respect of some designated Offices, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase **until 30 months** from the priority date (in some Offices even later); otherwise, the applicant must, **within 20 months** from the priority date, perform the prescribed acts for entry into the national phase before those designated Offices.

In respect of other designated Offices, the time limit of **30 months** (or later) will apply even if no demand is filed within 19 months.

See the Annex to Form PCT/IB/301 and, for details about the applicable time limits, Office by Office, see the *PCT Applicant's Guide*, Volume II, National Chapters and the WIPO Internet site.

Name and mailing address of the International Searching Authority
 European Patent Office, P.B. 5818 Patentlaan 2
 NL-2280 HV Rijswijk
 Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
 Fax: (+31-70) 340-3016

Authorized officer

Norbert Hiesch

DOCKETED

NOTES TO FORM PCT/ISA/220

These Notes are intended to give the basic instructions concerning the filing of amendments under article 19. The Notes are based on the requirements of the Patent Cooperation Treaty, the Regulations and the Administrative Instructions under that Treaty. In case of discrepancy between these Notes and those requirements, the latter are applicable. For more detailed information, see also the *PCT Applicant's Guide*, a publication of WIPO.

In these Notes, "Article", "Rule", and "Section" refer to the provisions of the PCT, the PCT Regulations and the PCT Administrative Instructions, respectively.

INSTRUCTIONS CONCERNING AMENDMENTS UNDER ARTICLE 19

The applicant has, after having received the international search report and the written opinion of the International Searching Authority, one opportunity to amend the claims of the international application. It should however be emphasized that, since all parts of the international application (claims, description and drawings) may be amended during the international preliminary examination procedure, there is usually no need to file amendments of the claims under Article 19 except where, e.g. the applicant wants the latter to be published for the purposes of provisional protection or has another reason for amending the claims before international publication. Furthermore, it should be emphasized that provisional protection is available in some States only (see *PCT Applicant's Guide*, Volume I/A, Annexes B1 and B2).

The attention of the applicant is drawn to the fact that amendments to the claims under Article 19 are not allowed where the International Searching Authority has declared, under Article 17(2), that no international search report would be established (see *PCT Applicant's Guide*, Volume I/A, paragraph 296).

What parts of the international application may be amended?

Under Article 19, only the claims may be amended.

During the international phase, the claims may also be amended (or further amended) under Article 34 before the International Preliminary Examining Authority. The description and drawings may only be amended under Article 34 before the International Examining Authority.

Upon entry into the national phase, all parts of the international application may be amended under Article 28 or, where applicable, Article 41.

When?

Within 2 months from the date of transmittal of the international search report or 16 months from the priority date, whichever time limit expires later. It should be noted, however, that the amendments will be considered as having been received on time if they are received by the International Bureau after the expiration of the applicable time limit but before the completion of the technical preparations for international publication (Rule 46.1).

Where not to file the amendments?

The amendments may only be filed with the International Bureau and not with the receiving Office or the International Searching Authority (Rule 46.2).

Where a demand for international preliminary examination has been/is filed, see below.

How?

Either by cancelling one or more entire claims, by adding one or more new claims or by amending the text of one or more of the claims as filed.

A replacement sheet must be submitted for each sheet of the claims which, on account of an amendment or amendments, differs from the sheet originally filed.

All the claims appearing on a replacement sheet must be numbered in Arabic numerals. Where a claim is cancelled, no renumbering of the other claims is required. In all cases where claims are renumbered, they must be renumbered consecutively (Section 205(b)).

The amendments must be made in the language in which the international application is to be published.

What documents must/may accompany the amendments?

Letter (Section 205(b)):

The amendments must be submitted with a letter.

The letter will not be published with the international application and the amended claims. It should not be confused with the "Statement under Article 19(1)" (see below, under "Statement under Article 19(1)").

The letter must be in English or French, at the choice of the applicant. However, if the language of the international application is English, the letter must be in English; if the language of the international application is French, the letter must be in French.

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference 189149 / PCT	FOR FURTHER ACTION see Form PCT/ISA/220 as well as, where applicable, item 5 below.	
International application No. PCT/US2008/057450	International filing date (day/month/year) 19/03/2008	(Earliest) Priority Date (day/month/year) 19/03/2007
Applicant THE GENERAL HOSPITAL CORPORATION		

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 4 sheets.

It is also accompanied by a copy of each prior art document cited in this report.

1. Basis of the report

a. With regard to the **language**, the international search was carried out on the basis of:

the international application in the language in which it was filed
 a translation of the international application into _____, which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b))

b. This international search report has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43.6bis(a)).

c. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, see Box No. I.

2. **Certain claims were found unsearchable** (See Box No. II)

3. **Unity of invention is lacking** (see Box No III)

4. With regard to the **title**,

the text is approved as submitted by the applicant
 the text has been established by this Authority to read as follows:

5. With regard to the **abstract**,

the text is approved as submitted by the applicant
 the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority

6. With regard to the **drawings**,

a. the figure of the **drawings** to be published with the abstract is Figure No. 2

as suggested by the applicant
 as selected by this Authority, because the applicant failed to suggest a figure
 as selected by this Authority, because this figure better characterizes the invention

b. none of the figures is to be published with the abstract

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B5/00 G01B9/02

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61B G01B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2004/054268 A1 (ESENALIEV RINAT [US] ET AL) 18 March 2004 (2004-03-18) paragraph [0003] - paragraph [0004] paragraph [0010] - paragraph [0015] paragraph [0038] - paragraph [0047] ----- US 2004/077949 A1 (BLOFGETT DAVID W [US] ET AL BLODGETT DAVID W [US] ET AL) 22 April 2004 (2004-04-22) paragraph [0002] paragraph [0010] - paragraph [0015] paragraph [0048] - paragraph [0057] paragraph [0066] - paragraph [0073] figures 3a, 3b ----- -/	1-9, 11-22, 24,25
X		1-8,10, 12-21, 23,25

Further documents are listed in the continuation of Box C.

See patent family annex.

* Special categories of cited documents :

- *A* document defining the general state of the art which is not considered to be of particular relevance
- *E* earlier document but published on or after the international filing date
- *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- *O* document referring to an oral disclosure, use, exhibition or other means
- *P* document published prior to the international filing date but later than the priority date claimed

- *T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- *X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- *Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- *&* document member of the same patent family

Date of the actual completion of the international search

1 July 2008

Date of mailing of the international search report

17/07/2008

Name and mailing address of the ISA/

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
Fax: (+31-70) 340-3016

Authorized officer

Montes, Pau

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 2002/140942 A1 (FEE MICHALE SEAN [US] ET AL) 3 October 2002 (2002-10-03) paragraph [0007] - paragraph [0009] paragraph [0019] - paragraph [0021] paragraph [0037] - paragraph [0039] figure 5 -----	1-25

Information on patent family members

International application no

PCT/US2008/057450

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2004054268	A1 18-03-2004	NONE	
US 2004077949	A1 22-04-2004	NONE	
US 2002140942	A1 03-10-2002	US 2005105096 A1	19-05-2005

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

see form PCT/ISA/220

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY
(PCT Rule 43bis.1)

		Date of mailing (day/month/year) see form PCT/ISA/210 (second sheet)
Applicant's or agent's file reference see form PCT/ISA/220		FOR FURTHER ACTION See paragraph 2 below
International application No. PCT/US2008/057450	International filing date (day/month/year) 19.03.2008	Priority date (day/month/year) 19.03.2007
International Patent Classification (IPC) or both national classification and IPC INV. A61B5/00 G01B9/02		
Applicant THE GENERAL HOSPITAL CORPORATION		

1. This opinion contains indications relating to the following items:

- Box No. I Basis of the opinion
- Box No. II Priority
- Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- Box No. IV Lack of unity of invention
- Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- Box No. VI Certain documents cited
- Box No. VII Certain defects in the international application
- Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Date of completion of this opinion see form PCT/ISA/210	Authorized Officer Montes, Pau Telephone No. +49 89 2399-7259
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Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of:
 the international application in the language in which it was filed
 a translation of the international application into , which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1 (b)).
2. This opinion has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43bis.1(a))
3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material:
 a sequence listing
 table(s) related to the sequence listing
 - b. format of material:
 on paper
 in electronic form
 - c. time of filing/furnishing:
 contained in the international application as filed.
 filed together with the international application in electronic form.
 furnished subsequently to this Authority for the purposes of search.
4. In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
5. Additional comments:

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/US2008/057450

**Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or
industrial applicability; citations and explanations supporting such statement**

1. Statement

Novelty (N)	Yes: Claims	<u>5,11,18,24</u>
	No: Claims	<u>1-4,6-10,12-17,19-23,25</u>
Inventive step (IS)	Yes: Claims	
	No: Claims	<u>1-25</u>
Industrial applicability (IA)	Yes: Claims	<u>1-25</u>
	No: Claims	

2. Citations and explanations

see separate sheet

Re Item V.

1 Reference is made to the following documents:

D1: US 2004/054268 A1 (ESENALIEV RINAT [US] ET AL) 18 March 2004 (2004-03-18)

D2: US 2004/077949 A1 (BLOFGETT DAVID W [US] ET AL BLODGETT DAVID W [US] ET AL) 22 April 2004 (2004-04-22)

2 The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claims 1-4, 6-10, 12-17, 19-23 and 25 is not new in the sense of Article 33(2) PCT.

2.1 Independent apparatus claim 1 is not new over the disclosure of document D1. This document discloses (the references in parentheses applying to this document):

- an apparatus for determining at least one characteristic of an anatomical structure (see par. [0003]), comprising:
- a first opto-acoustic arrangement which is configured to cause a generation of an acoustic wave in the anatomical structure (see par. [0010]); and
- a second arrangement which is configured to detect the acoustic wave and determine whether at least one blood pool is present at or in the anatomical structure as a function of at least one property of the acoustic wave (see par. [0010]; it is not clear which technical restriction the fact that the arrangement is "configured to determine whether one blood pool is present" confers, it appears that this sentence merely describes a result to be achieved).

2.2 Independent claim 12 defines a method comprising the steps carried out by the sub-units of the device defined in claim 1. However, document D1 also discloses the corresponding method (see par. [0003]). As a consequence, the subject-matter of claim 12 also lacks novelty in view of document D1.

2.3 Independent apparatus claim 13 and its corresponding independent method claim 25 are

also not new over the disclosure of document D1 (see passages cited under point 2.1 and par. [0047]).

2.4 The attention of the applicant is drawn to the fact that the subject-matter of claims 1, 12-13 and 25 is also known from document D2 (see pars. [0002], [0010] and [0012]).

2.5 The additional features of dependent claims 2-4, 6-10, 14-17, 19-23 are disclosed in documents D1 or D2. The corresponding passages are the following:

- for claim 2-4, 6, 15-17 and 19: see par. [0047] in D1 or par. [0012] in D2; the additional technical features of claims 3-4, 6, 16-17 and 19 merely describe the working principle of an interferometer and are therefore implicitly disclosed
- for claims 7 and 20: interferometric methods are based on interfering a detected radiation with a reference. However, in claims 7 and 20 no reference is mentioned so that it is not clear whether a third radiation is needed. It seems therefore that an essential feature is missing in the formulation of claims 7 and 20. The description does not provide any further help to interpret the meaning of said claims (see par. [0013] of the description). As a consequence, the subject-matter of said claims does not add any clear technical restriction to the subject-matter of claims 2 and 14, respectively, and is therefore known from D1 as well as from D2
- for claims 8, 14 and 21: claims 8, 14 and 21 do not add any clear technical restriction to the subject-matter of claims 2 and 13. The subject-matter of claims 8, 14 and 21 is therefore not new in

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING
AUTHORITY (SEPARATE SHEET)**

International application No.

PCT/US2008/057450

- for claims 9 and 22:
view of D1 as well as of D2
see par. [0011] in D1
- for claims 10 and 23:
see pars. [0066] and [0067] in D2

2.6 The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claims 5, 11, 18 and 24 does not involve an inventive step in the sense of Article 33(3) PCT.

- for claims 5 and 18:
the subject-matter of claims 5 and 18 is not clear. The meaning of term "sideband" cannot be unambiguously discerned from the formulation of the claims in view of the description. Furthermore, it is not clear what is meant by a "fundamental frequency". This lack of clarity notwithstanding, claims 5 and 18 appear to define the working principle of frequency domain interferometry which is well known in the art
- for claims 11 and 24:
mapping measurements to a location to generate an image of one portion of a tissue is well-known in the art and does not imply an inventive step

Possible steps after receipt of the international search report (ISR) and written opinion of the International Searching Authority (WO-ISA)

General information	For all international applications filed on or after 01/01/2004 the competent ISA will establish an ISR. It is accompanied by the WO-ISA. Unlike the former written opinion of the IPEA (Rule 66.2 PCT), the WO-ISA is not meant to be responded to, but to be taken into consideration for further procedural steps. This document explains about the possibilities.
Amending claims under Art. 19 PCT	Within 2 months after the date of mailing of the ISR and the WO-ISA the applicant may file amended claims under Art. 19 PCT directly with the International Bureau of WIPO. The PCT reform of 2004 did not change this procedure. For further information please see Rule 46 PCT as well as form PCT/ISA/220 and the corresponding Notes to form PCT/ISA/220.
Filing a demand for international preliminary examination	In principle, the WO-ISA will be considered as the written opinion of the IPEA. This should, in many cases, make it unnecessary to file a demand for international preliminary examination. If the applicant nevertheless wishes to file a demand this must be done before expiry of 3 months after the date of mailing of the ISR/ WO-ISA or 22 months after priority date, whichever expires later (Rule 54bis PCT). Amendments under Art. 34 PCT can be filed with the IPEA as before, normally at the same time as filing the demand (Rule 66.1 (b) PCT). If a demand for international preliminary examination is filed and no comments/amendments have been received the WO-ISA will be transformed by the IPEA into an IPRP (International Preliminary Report on Patentability) which would merely reflect the content of the WO-ISA. The demand can still be withdrawn (Art. 37 PCT).
Filing informal comments	After receipt of the ISR/WO-ISA the applicant may file informal comments on the WO-ISA directly with the International Bureau of WIPO. These will be communicated to the designated Offices together with the IPRP (International Preliminary Report on Patentability) at 30 months from the priority date. Please also refer to the next box.
End of the international phase	At the end of the international phase the International Bureau of WIPO will transform the WO-ISA or, if a demand was filed, the written opinion of the IPEA into the IPRP, which will then be transmitted together with possible informal comments to the designated Offices. The IPRP replaces the former IPER (international preliminary examination report).
Relevant PCT Rules and more information	Rule 43 PCT, Rule 43bis PCT, Rule 44 PCT, Rule 44bis PCT, PCT Newsletter 12/2003, OJ 11/2003, OJ 12/2003